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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,900	02/12/2002	Isabelle Arnould-Reguigne	03806.0537	3572

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EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,900	ARNOULD-REGUIGNE ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 12-13, 16-25, 31-32, and 40, drawn to nucleic acids, vectors, host cells, kits and pharmaceutical compositions comprising the same, classified in class 536, subclass 23.1 and/or class 424/93.1, for example.

II. Claims 10-11 and 14-15, drawn to nucleic acid detection methods, classified in class 435, subclass 6 or 91.2.

III. Claims 26 and 34-35, drawn to polypeptides, classified in class 530, subclass 350.

IV. Claims 27-28 and 30, drawn to antibodies, classified in class 530, subclass 387.1.

V. Claim 29, drawn to methods of detecting polypeptides, classified in class 435, subclass 7.1.

VI. Claim 33, drawn to method for manufacturing a medicament, classified in class 514, subclass 44.

VII. Claims 36-39, drawn to methods of screening for active ingredients, classified in class 436, subclass 501.

Further Restriction Applicable to All Groups

Each group detailed above reads on 2 patentably distinct groups, wherein each of the distinct groups is drawn either nucleic acids or proteins or related products having to do with either (a) SEQ ID NO: 1 and 3 which encode SEQ ID NO: 3 or (b) SEQ ID NO: 2 and SEQ ID NO: 4 which encode SEQ ID NO: 6. For whichever group is elected, applicant must elect one

of (a) or (b) for further prosecution. For example, if group I is elected, and applicant elects (a), prosecution will be limited to claims which recited nucleic acids SEQ ID NO: 1 or SEQ ID NO: 3, and nucleic acids encoding SEQ ID NO: 3. If group II is elected, and applicant elects (a), methods of detection of the nucleic acid of group (a) will be examined. Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims. Applicant is advised that examination will be restricted to only the elected SEQ ID NOs and should not to be construed as a species election.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II and inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids (and vectors) of invention I can be used in a variety of methods such as to express encoded polypeptides and in nucleic acid purification assays.

3. The inventions of Groups I, III, and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group II is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group IV is also composed of

amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. Furthermore, the products of Groups I, II, and IV can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group IV can be used in immunoassay, the polypeptide of Group II can be used to make fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I, III, and IV are patentably distinct from each other.

4. Inventions I and V and inventions I and VII are unrelated. Inventions II and III, inventions II and IV, inventions II and V, inventions II and VI, and inventions II and VII are unrelated. Inventions III and VI are unrelated. Invention IV is unrelated to inventions VI and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the nucleic acids of invention I are not disclosed as being used in or necessary for the methods of detection or screening of inventions V and VII. Likewise, the amplification methods of invention II are not disclosed as used with or necessary for the products of inventions III and IV or the methods of inventions V, VI, and VII. The products of invention III are unrelated to the methods of manufacture of invention VI because they are not disclosed as used in the methods or necessary for the practice of the methods. The products of invention IV are unrelated to the methods of

inventions VI and VII because they are not disclosed as used in the methods or necessary for the practice of the methods.

5. Inventions III and V and inventions III and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of invention III can be used in a variety of methods, including the two recited herein, as well as, for example, methods for raising antibodies or methods of treatment.

6. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention IV can be used in a variety of methods, including methods of treatment and for making fusion proteins.

7. Inventions V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are each separate methods with different modes of operation, different functions and different effects.

8. With regard to the restriction between individual sequences, each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because they do

not share a common structure. The nucleic acids encode different polypeptides and the polypeptides themselves do not share a common structure. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

10. A telephone call was made to 5/9/03 on Ernest Chapman to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet Einsmann Switzer whose telephone number is (703) 306-

5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet Einsmann Switzer
Examiner
Art Unit 1634

May 15, 2003

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600